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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/576,781

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Ramin Shahidi

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EXAMINER

BRUTUS, JOEL F

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/576,781	Applicant(s) SHAHIDI, RAMIN	
	Examiner JOEL F. BRUTUS	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. Claim 26 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 4 of copending Application No. 10,576,632. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10,576,632. Although the conflicting claims are not identical, they are not patentably distinct from each other because.

Regarding claim 1, co-pending claim 1 teaches all other limitations; except "from a user receiving an indication of a target site on the captured image".

However, the co-pending claim includes identifying a spatial feature indication of a patient target site on the ultrasonic image. This limitation is just another way of wording the above limitation. The identification would have to be performed by a user.

It would have be obvious to one with ordinary skill in the art to modify co-pending claim 1 by creating a field of view; in order to monitor the instrument within the patient with increased visualization and accuracy.

Regarding claims 2-22, they are rejected because they depend on a rejected claim.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-10, 17-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Shahidi (US Pat: 6,167,296).

Regarding claim 1-5, and 21-22, Shahidi teaches FIG. 1 patient's head 112, has a tumor or lesion 117, which is the target object of the operation [see column 5 lines 30-34]. Fiducial markers 113, 114 are attached to the head to enable registration of images generated by previously obtained scan data according to techniques familiar to persons of ordinary skill in the relevant art. A surgical probe or instrument 109 held by the surgeon is directed toward the tissues of interest. A computer 101 is connected to user input devices including a keyboard 103 and mouse 104, and a video display device 102 which is preferably a color monitor. The display device 102 is located such that it can be easily viewed by the surgeon during an operation, and the user input devices 103 and 104 are placed within easy reach to facilitate use during the surgery [see column 5 lines 35-45]. Data are produced normally using polar or spherical coordinates to specify locations in the region of interest, and the program converts this data preferably to Cartesian coordinates [see column 8 lines 59-62].

Shahidi teaches that the apparatus further includes a position tracking system, which is preferably an optical tracking system (hereafter "OTS") having a sensing unit

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105 mounted overhead in view of the operating table scene, and at least two light emitting diodes (LED's) 110, 111 mounted on the surgical instrument 109. These LED's preferably emit continuous streams of pulsed infrared signals which are sensed by a plurality of infrared sensors 106, 107, 108 mounted in the sensing unit 105 in view of the surgical instrument 109. The instrument 109 and the sensing unit 105 are both connected to the computer 101, which controls the timing and synchronization of the pulse emissions by the LED's and the recording and processing of the infrared signals received by the detectors 106-108 [see column5 lines 47-53]. The OTS further includes software for processing these signals to generate data indicating the location and orientation of the instrument 109. The OTS generates the position detecting data on a real time continuous basis, so that as the surgical instrument 109 is moved, its position and orientation are continually tracked and recorded by the sensing unit 105 in the computer 101, other position tracking systems, such as sonic position detecting systems, may also be utilized [see column 5 lines 60-65].

. Regarding claims 5-10, all other limitations are taught as set forth by the above teaching. Shahidi teaches rotating the instrument and transducer about this axis, US scan data is collected and stored for a cone-shaped volume in the region of interest. This cone defines the "field of view" of the transducer scan [see column 7 lines 36-53]. Data are produced normally using polar or spherical coordinates to specify locations in the region of interest, and the program converts this data preferably to Cartesian coordinates [see column 8 lines 59-62]. Applicant discloses that spatial target site indicated can be a volume, area, or point [see 0012]; Figs 1, 10-14A show the target

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site as a point (denoted as numeral 117) and arranged in geometric pattern defining a boundary of the tumor (indicated area) [see fig 1, 10-14A].

Referring now to FIG. 10, the drawing shows a highly simplified sketch of a three-dimensional image display obtained by the above system with the endoscope of FIG. 1 in the alternative position shown by the dotted lines, pointing toward the target lesion or tumor. The display has been manipulated to provide a three-dimensional sectional view with a cutting plane passing through the tip of the endoscope and orthogonal to its axis. Again, the endoscope field of view 905 is indicated in the display, and in a preferred embodiment auxiliary displays are also presented showing the actual image seen by the endoscope in the field of view, and the 3D perspective image for the same region in the field of view; these auxiliary displays are also not shown in FIG. 10. This Figure further preferably includes also the conventional axial, coronal and sagittal 2D displays for purposes of further clarification and elucidation [see column 10 lines 46-63].

Regarding claims 17-20, Shahidi teaches an indicia of a first target site (which is the tumor denoted 117 in fig 1) and a second target or entry point (which is an incision denoted by dotted lines 116 in fig 1) through which the instrument is inserted to reach the tumor or to provide the surgical trajectory [see column 2 lines 1-5].

Regarding claims 23-26, all other limitations are taught as set forth by Shahidi above. Shahidi further teaches FIG. 7 is a schematic block diagram of a flow chart for a program that implements the ultrasound intra-op protocol. The program starts by causing the computer to receive and load the data from a US transducer at the tip of

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the surgical instrument [see column 8 lines 59-62]. Next, optical tracking system data is read to determine the position and orientation of the surgical instrument and US data from the aggregation of aligned data slices is utilized to reconstruct 3D image data representing the US scan data. This image data is manipulated and transformed by the program in a manner similar to the manipulation of the pre-op data, and the resulting image is displayed [see column 8 lines 55-65].

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shahidi (US Pat: 6,167,296) stand alone.

Regarding claims 11-14, all other limitations are taught as set forth by the above teaching.

Shahidi doesn't specifically teach spacing between indicia is indicative of distance of instrument from the target.

However, Shahidi teaches determining the orientation and location of the instrument with the LED's that are mounted on the instrument; and with a plurality of fiducial markers that placed on the patient head near the tumor and register these data into a computer to provide predetermined known coordinates informations [see above].

Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to combine these references; for the purpose of precisely monitor the location and orientation of the instrument and the target site.

Regarding claims 15-16, all other limitations are taught as set forth by the above teaching. Shahidi teaches an indicia of a first target site (which is the tumor denoted 117 in fig 1) and a second target or entry point (which is an incision denoted by dotted lines 116 in fig 1) through which the instrument is inserted to reach the tumor or to provide the surgical trajectory [see column 2 lines 1-5]. Fig 1 teaches an incision mimicking the shape and size of the instrument [see fig 1]. The shape and size of the incision would provide an indication of an orientation of the instrument.

Therefore, one with ordinary skill in the art at the time the invention was made would have been able to the shape and size of the incision would provide an indication of an orientation of the instrument; in order to determine the optimal surgical trajectory and to prevent or minimize trauma of puncture any other surrounding anatomical structure.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is (571)270-3847. The examiner can normally be reached on Mon-Fri 7:30 AM to 5:00 PM (Off alternative Fri).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. B./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768